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ABSTRACT:

Disclosed is a connector system for medical applications such as intravenously introducing medication into a patient. In intravenous applications a feeding system is employed through which parenteral liquid flows into the patient intravenously via a needle attached at one end to the feeding system and having its pointed end inserted into the patient's vein. The feeding system includes a port at the end of a conduit which has a seal associated with it which closes said port but is adapted to be penetrated by a second needle. This second needle is connected to a source of medication which flows through the second needle and mixes with the parenteral liquid flowing into the patient. A cap member is secured to the port and it carries within a cavity the second needle which penetrates the seal when the cap member is covering the port. Because the cap is secured to the port, movement of the patient will not result in the second needle being pulled from the seal. The needle is lodged deep within the cavity so that if the cap is placed, for example, on the patient's bed, the needle will not directly contact bacteria which may be on the bed. To avoid scraping material from the internal conduit walls with the needle, a potentially lethal event, the cap member serves as a guide which directs the needle into the center of the seal, well away from the internal conduit walls.

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(54) **Medical connector system.**

(57) Disclosed is a connector system for medical applications such as intravenously introducing medication into a patient. In intravenous applications a feeding system is employed through which parenteral liquid flows into the patient intravenously via a needle attached at one end to the feeding system and having its pointed end inserted into the patient's vein. The feeding system includes a port at the end of a conduit which has a seal associated with it which closes said port but is adapted to be penetrated by a second needle. This second needle is connected to a source of medication which flows through the second needle and mixes with the parenteral liquid flowing into the patient. A cap member is secured to the port and it carries within a cavity the second needle which penetrates the seal when the cap member is covering the port. Because the cap is secured to the port, movement of the patient will not result in the second needle being pulled from the seal. The needle is lodged deep within the cavity so that if the cap is placed, for example, on the patient's bed, the needle will not directly contact bacteria which may be on the bed. To avoid scraping material from the internal conduit walls with the needle, a potentially lethal event, the cap member serves as a guide which directs the needle into the center of the seal, well away from the internal conduit walls.

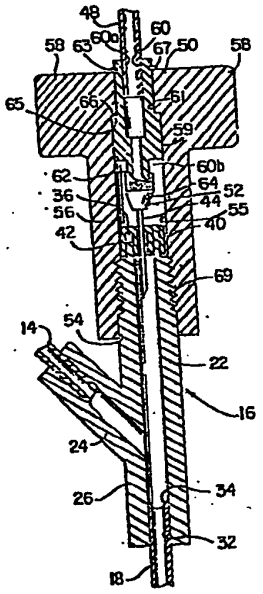

FIG. 4

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C 5165-EP

MEDICAL CONNECTOR SYSTEM

RELATED PATENT APPLICATION

This application is a continuation-in-part application of U.S. Patent Application Serial No. 06/460,585, filed January 24, 1983, and entitled "Device for Intravenously Introducing Medication Into a Patient."

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to connector systems used in the treatment of the injured or sick, and in particular to devices for intravenously introducing medication into a patient in a safe, convenient way.

2. Discussion of Prior Art

It is a common practice in treating patients, particularly patients who must be cared for under emergency conditions, with medication introduced into the patient intravenously. An intravenous solution, commonly referred to as the parenteral liquid, is fed from a container supplying this liquid through tubing via a needle which has been inserted into the patient's vein. The needle is taped securely to the patient's arm and is not likely to pull from the patient's arm if the patient moves. Medication needed to sustain the life of the patient, for example, drugs which maintain the blood

pressure of the patient at the desired level, are added to the parenteral liquid. The conventional practice is to insert a needle into a sealed entry port in a connector through which the parenteral liquid flows. The way the needle is currently inserted into the sealed port, however, permits the needle to be pulled loose from the seal relatively easily. This presents a problem which, though recognized by the manufacturers of conventional intravenous type medical devices, has not as yet been adequately solved. The accidental removal of the needle from the sealed port can have very serious consequences and could even lead to the death of the patient being treated.

Another problem with treating patients is infection. All too often a patient's life is seriously endangered by bacteria gaining entry into a patient's system, infecting the patient. In a vast number of cases it is unknown how the bacteria gain entry. We have observed conditions in hospitals and identified that one likely way the bacteria gain entry is by contamination of the needle inserted into the sealed entry port. This happens when the attendant notices that the needle has pulled loose and simply reinserts it even though it may now have on its surface bacteria picked up by direct contact with, for example, the patient's bedding.

SUMMARY OF THE INVENTION

We have recognized that the above situation presents a serious health hazard to patients, and have now provided an economical, convenient, and safe medical connector system useful in treating patients. In addition to having utility for administering medication intravenously, the connector system of the present invention may be employed in a wide variety of applications

where it is desirable to minimize bacterial infection. For example, it may be used with catheters or chest tubes.

In intravenous systems, it includes a feeding system through which the parenteral liquid flows into the patient intravenously. The feeding system has a conduit with a port therein, including seal means which close the port. The seal means is adapted to be penetrated by a needle which is connected to a source of the medication. According to our invention, a cap member is secured to the port, and this cap member carries the needle which penetrates the seal means. Since the cap member is secured to the port, movement of the patient does not result in removal of the needle from the seal means. The needle is also mounted within a chamber or cavity in the cap member in a way which avoids or reduces the likelihood of contamination. Furthermore, the interior walls of the cap engaging the exterior walls of the mating conduit provide a guideway that directs the needle into the center of the seal means to ensure that the needle does not scrape against the inside walls of the conduit. Particles scraped from the inside conduit wall could make their way into the patient's blood stream and result in death. This potentially lethal condition is inherent in the design of certain prior art devices, but the connector system of this invention with its mating conduit wall design so directs the needle to avoid scraping against the inside connector walls.

The connector system of this invention has several advantages. First, it is easy to manufacture and convenient to use. Secondly, and most importantly, it provides a safe way for administering medication intravenously to a patient, because (a) the cap is held securely in position, so that the needle cannot be

jarred loose by movement of the patient, (b) the cap is designed to guide the needle so that it does not scrape against the inside of the conduit walls, and (c) the connector system is designed to minimize the likelihood of contamination of the needle carried by the cap member.

BRIEF DESCRIPTION OF THE DRAWING

The features of the present invention can best be understood, together with the advantages discussed above and other advantages, by reference to the following description taken in connection with the drawing wherein like numerals indicate like parts.

Figure 1 is a schematic view illustrating administering medication intravenously to a patient in accordance with conventional practice.

Figure 2 is a cross-sectional view of a Y-type connector for introducing parenteral liquid and medication intravenously to the patient as shown in Figure 1.

Figure 3 is a perspective view of the connector system of the present invention.

Figure 4 is a cross-sectional view of the connector system of the present invention taken along line 4-4 of Figure 3.

Figure 5 is a perspective view of an alternate embodiment of the connector system of the present invention.

Figure 6 is a cross-sectional view of the connector system of the present invention taken along line 6-6 of Figure 5.

DETAILED DESCRIPTION OF THE DRAWING

As shown in Figures 1 and 2, parenteral liquid is introduced into a patient intravenously via a feeding system 10. The feeding system 10 includes a container 12

for the parenteral liquid, a tube 14 extending from the container and connected to a Y-connector 16, and a tube 18 from the Y-connector to a needle (not shown) inserted into a vein of the patient. The needle is taped to the patient so that movement of the patient will not result in the needle being pulled from the patient's vein.

As best illustrated in Figure 2, medication from container 20 is introduced into the parenteral liquid flowing through the feeding system 10 at the Y-connector 16. This Y-connector 16 consists of two tubular conduits 22 and 24 which merge into a third tubular conduit 26. The tubing 14 from the container 12 of parenteral liquid is inserted into the inlet port 28 of the conduit 22 and secured in position, for example, by an adhesive which bonds the external surface of this tube to the internal wall surface of the conduit. There is a stop 30 which limits the extent to which this tube 14 can be inserted into the conduit. In a similar fashion, the tube 18 is secured to the outlet port 32 of the Y-connector. This tube 18 is inserted into the outlet port 32 until it abuts a stop 34 in the internal wall of the conduit. This tube 18 is then secured by an adhesive to the internal wall of the conduit 26. The branch conduit 24 has a latex seal 36 at its inlet port 38 which seals this port. Consequently, bacteria cannot enter the Y-connector 16 via the inlet port 38, because of the seal 36. This seal 36 is of conventional design and includes coaxial annular aprons 40 and 42 which fit over the conduit wall and grip the external and internal wall surfaces to hold the seal securely to the conduit 24.

The medication is introduced into the parenteral liquid flowing through the Y-connector 16 by a needle 44 which is inserted through the central part of the seal 36 into the branch conduit 24. This needle 44

is connected by a suitable connector 46 to a tube 48 which is connected to the container 20 (Figure 1) for the medication. As parenteral liquid flows through the Y-connector 16 into the inlet port 28 and out the outlet port 32, the medication is drawn into this stream of parenteral liquid, flowing from the container 20 via the tube 48 and through the open end of the needle 44 into the parenteral liquid.

The problem with the conventional device shown in Figure 2 is that if the patient moves, for example, rolls or moves his or her arm, the needle 44 may be pulled from the seal 36. If this occurs, the latex seal 36 has sufficient resiliency to close off the hole in the seal produced by the needle 44. The parenteral liquid will continue to flow into the patient's system, but the necessary medication is no longer being introduced into it. The consequences of this condition are very grave and, if this condition is unnoticed by an attendant, it could result in the death of the patient or serious complications in the patient's treatment. Even if the attendant notices that the needle 44 has been removed from the seal 36 and reinserts it into the seal, it is possible that the needle has been contaminated with bacteria. Consequently, the use of such a contaminated needle 44 is unacceptable.

In accordance with the present invention, as illustrated in Figures 3 and 4, the needle 44 is secured to the Y-connector 16 so that movement of the patient does not result in the needle being pulled from the seal 36. The parenteral liquid is introduced via the conduit 24 and the conduit 22 is designed to receive the seal 36, with a cap member 50 carrying the needle 44 being secured to the conduit 22 so that the cap member covers the inlet port 28 and the needle penetrates the seal covering the port.

The function of the cap member 50 is threefold: First, it secures the needle 44 in position so that movement of the patient will not result in it being removed from the seal 36. Secondly, the cap member 50 surrounds the needle 44 and provides a cavity 52 in which the needle 44 is lodged so that it does not project beyond the open end 54 of the cavity. Because the needle 44 is so lodged within the cavity 52, if the attendant did, for example, lay the cap member on the patient's bed, the needle would not come into direct contact with the bed which might be infested with harmful bacteria. Thus this arrangement of the needle 44 deep within the cavity in the cap member provides additional protection for the patient. Third, the cap member 50 in coacting with the exterior wall of conduit 22 guides the needle into the center of the seal 36. Consequently, the needle does not scrape the inside wall of conduit 22 so that particles of plastic are not introduced into the patient's circulatory system. Such particles could cause death.

The cap member 50 comprises a cylindrical connector section 56 having a hollow interior forming the chamber or cavity 52. The needle, being disposed lengthwise along the longitudinal axis of the cavity, is centrally located within the cavity. Near the end 54 the interior walls 55 of the connector section 56 are threaded. As the cap member 50 is screwed onto the conduit 22, the interior cavity wall 55, sliding over the exterior surfaces of the conduit, serve to guide the needle 44 so that it penetrates the center of the seal. Thus, the cap member 50 and conduit 22 mate in a male-female relationship, with the needle always being housed safely within the center of the cavity in an unexposed condition. In this embodiment the cap member serves as the female component. To further insure that the

needle 44 penetrates the center of the seal 36, the threads 69 could be lowered further below the seal so that the cap member would fit telescopically over the conduit 22 and then be screwed into position.

The top of the cap member 50 has a pair of outwardly extending wings 58 which facilitate screwing the cap member to the conduit 22. A spindle 59 is received within an opening 61 within the cap member 50. The body of the spindle 59 has a cylindrical neck section having a groove 63 in an end which protrudes from the opening 61. The cylindrical body expands outwardly slightly to provide a shoulder 65 which engages a stop 66 when the spindle 59 is placed in the opening, and a TRU seal C-ring 67 is received in the groove 63 to hold the spindle in position but allowing the cap member to revolve about the spindle as it is screwed onto the Y-connector 16.

Along the longitudinal axis of the spindle 59 is a passageway 60. The tube 48 from the container 20 containing the medication is inserted into the one end 60a of the passageway 60 and bonded to the internal surface of this passageway, for example, by means of an adhesive. The other end 60b of the passageway terminates in a threaded connector section 62 to which the needle 44 is secured. This needle has an adapter 64 which has an internal thread which engages the threads of the connector section 62. The hollow needle 44 extends outwardly from this adapter 64 and penetrates the seal 36 as the cap member 50 is secured to the conduit 22 by screwing it onto the conduit 22 to engage threads 69 on the external surface of the conduit just below the seal 36. Thus the needle 44 is held secure to the Y-connector 16, penetrating the center of the seal 36 with its point safely displaced away from the inside wall 55 of the conduit 22.

As shown in Figures 5 and 6, an alternate embodiment of the present invention is shown wherein the cap member is simply snapped on to the Y-connector 16, thereby eliminating the necessity of using a threaded cap member and threaded Y-connector. In accordance with this embodiment of the invention, the cap member 70 includes a hollow cylindrical element 72 which carries on its exterior two hingedly mounted clips 74 which have catch tips 76 which snap into a groove 78 in the external wall of the conduit 22. A plug assembly 80 carries the tubing 48 and the needle 44, which is mounted on an adapter 64 such as shown in Figure 4. This plug assembly 80 is glued or otherwise bonded to the open end of the cylindrical member 72.

To attach the cap member 70, one simply slips the cap 70 over the conduit 22. The clips 74 bend outwardly slightly and when the catch tips 76 of the clips are opposite the groove 78, the clips snap in place as shown in solid lines in Figure 6. In accordance with one of the features of this invention, the centrally mounted needle 44 is guided into the center of the seal 36 by the cap member 70, which, like a telescope, slides over the tubular conduit 22. There is a shoulder 82 which serves as a stop to limit the movement of the cap member. This shoulder 82 brings the catch tips 76 of the clips 48 into registration with the groove 78 in the conduit 22 and, because of the internal bias due to the resiliency of the material from which these clips are made, they snap into a locking position, locking the cap member to the conduit. The cap member 70 including clips 74 are made from, for example, Nylon, which is a material having the desired resiliency. To release the cap member from the Y-connector 16, the clips 74 are simply depressed and the cap member 70 is removed from the Y-connector.

As will be appreciated from the above description, there is inherent in the cap member 70 two functions in a single structure. Namely, the cap member 70 provides the cavity 52 which guards the needle 44 against contamination and guides the needle into the center of the seal 36, away from the inside wall of the conduit 22. Thus, the attendant may conveniently and safely attach and detach the cap member, without any extra steps or risk to the patient. Because of this feature, this invention may be used under normal working conditions without creating any additional work for the attendant, while substantially reducing the likelihood of harm to the patient due to carelessness.

The above description presents the best mode contemplated of carrying out the present invention. This invention is, however, susceptible to modifications and alternate constructions from the embodiments shown in the drawing and described above. Consequently, it is not the intention to limit this invention to the particular embodiments disclosed. On the contrary, the intention is to cover all modifications and alternate constructions falling within the spirit and scope of the invention as expressed in the appended claims.

The following part of the description are preferred embodiments 1 - 31 presented in the format of claims.

1. A connector system for intravenously introducing medication into a patient, comprising:

a cap member having a cavity therein in which is lodged a needle in a manner whereby the needle is recessed within the cavity,

a branch connector having a first inlet port adapted to be connected by tubing means to a source of parenteral liquid, an outlet port through which the parenteral liquid flows via tube means into the patient, and a second inlet port having seal means which is adapted to be penetrated by the needle, said medication flowing from a source through the needle into the parenteral liquid flowing through the connector, and

means coupling the second inlet port and the cap member securely together, with the needle penetrating the seal means, whereby movement of the patient does not result in the removal of the needle from the seal means.

2. The connector system of Claim 1 wherein the internal walls of the cap member guide the needle so that said needle penetrates the central portion of seal means as the cap member is fitted over the second inlet port and does not scrape against the connector.

3. The connector system of Claim 2 wherein the cavity provides a chamber which surrounds the needle, with said needle being lodged within the chamber so that it is not likely to be contaminated.

4. The connector system of Claim 3 wherein the cap member is screwed onto the second inlet port, said cap member having internal threads which engage external threads adjacent the second inlet port.

5. The connector system of Claim 4 wherein the cap member has outwardly extending wings that permit the cap means to be easily screwed onto the second inlet port.

6. The connector system of Claim 3 wherein the cap member is of the snap-on type wherein said cap member has clip means attached thereto for detachably connecting the cap member to the connector.

7. A connector system for introducing medication into a patient, comprising:

feeding means through which liquid flows into the patient, said feeding means having a port therein including seal means which close said port, said seal means being adapted to be penetrated by a needle, and

a cap member secured to the port, said cap member having a cavity therein which forms a chamber in which is lodged a needle which does not project beyond an open end of the cavity, said needle penetrating the seal means when the cap member is covering the port, with said medication being fed through the needle into the liquid flowing into the patient.

8. The connector system of Claim 7 wherein the feeding means is a Y-type connector having a pair of conduits which merge into a single conduit, each of said conduits having a port, and one of these ports having the seal means.

9. The connector system of Claim 8 wherein the seal means includes apron means which grips the walls of the conduit adjacent the port having the seal means.

10. The connector system of Claim 9 wherein there are threads on the external conduit wall adjacent the apron means.

11. The connector system of Claim 10 wherein the cap member includes internal threads which engage the external threads on the conduit wall when the cap member is screwed onto the port.

12. The connector system of Claim 7 wherein the assembly of the feeding means and cap member includes snap-on type coupling means detachably securing the assembly together, said snap-on type coupling means which allows the coupling means to be movable between a release position for separating the feeding means and the cap member and a holding position locking the feeding means and cap member together.

13. The connector system of Claim 7 wherein the feeding means includes a tubular conduit having an end covered by the seal means and the needle is centrally lodged in the cavity, and said cavity has internal side walls which fit snugly around the tubular conduit and guide the needle into the central part of the seal means when the cap member is placed on the conduit.

14. The connector system of Claim 13 wherein the cap member and conduit engage in a male-female mating relationship when the cap member is placed on the conduit member.

15. The connector system of Claim 14 wherein the cap member functions as a female component.

16. A connector system used in the treatment of a patient, comprising:

feeding means having a tubular conduit member serving as a male component and having an open end sealed by seal means which close off the open end, said seal means being adapted to be penetrated by a needle, and

a cap member removably secured to the conduit, said cap member serving as a female component and having a cavity therein in which is centrally lodged a needle, said cavity having internal side walls which fit snugly around the tubular conduit member and guide the needle into the central portion of the seal means when the cap member and conduit interact in a male-female mating relationship when the cap is placed on the conduit member.

17. The connector system of Claim 16 wherein the needle is lodged within the cavity along the longitudinal axis of the cavity.

18. The connector system of Claim 17 wherein the needle does not project from the cavity.

19. A cap member for connecting a source of medication to a tubular conduit, comprising:

a connector section having a hollow interior which forms a chamber, and

a needle disposed lengthwise within the chamber and of a length such that it does not protrude beyond the chamber.

20. The cap member of claim 19 wherein the connector section is cylindrical and the needle is deposed along the longitudinal axis of the cylindrical connector section.

21. The cap member of claim 19 wherein the connector section is designed to engage in a male-female mating relationship with the tubular conduit when connected to the feeding system.

22. A connector system for coupling a feeding system to a source of medication wherein the feeding system includes a sealed tubular conduit, said device comprising:

a cap member which is adapted to be connected to the tubular conduit and which carries a needle which penetrates the sealed tubular conduit when the cap member is connected to the conduit;

said cap member including means for guiding the needle during insertion so that it can not scrape against the inside wall of the conduit and for protecting the needle from direct contact with objects that may contaminate the needle when the cap member and tubular conduit are disconnected; and

means for securely, but detachably, holding the cap to the tubular conduit.

23. The connector system of Claim 22 wherein the cap member includes a chamber in which the needle is lodged, said needle being of a length such that it does not project from the chamber.

24. The connector system of Claim 23 wherein the chamber has a generally cylindrical shape and the needle is disposed along the longitudinal axis of the cylindrical chamber.

25. The connector system of Claim 24 wherein the tubular conduit and cap member are designed to engage in a male-female mating relationship when the cap member is connected to the tubular conduit.

26. The connector system of Claim 25 wherein the needle penetrates the center of the sealed tubular conduit when the cap member is connected to the conduit.

27. A connector system comprising:

first conduit means having an open end, seal means at the open end of the first conduit and sealing said open end, said seal means being of the type that is adapted to be penetrated by a needle, and

second conduit means having at one end means for coupling the first and second conduits together, said coupling means including a cap member adapted to fit over the end of first conduit means and having a cavity therein which forms a chamber in which is lodged a needle that does not project beyond an open end of the cavity, said needle penetrating the seal means when the first and second conduit means are coupled together.

28. The connector system of Claim 27 wherein the needle is centrally lodged in the cavity, and said cavity has internal side walls which fit snugly around the second conduit means.

29. The connector system of Claim 28 wherein the cap member and second conduit means engage in a male-female mating relationship when the cap member is placed on said conduit means.

30. The connector system of Claim 29 wherein the cap member functions as a female component.

31. The connector system of Claim 30 wherein the internal walls of the cavity serve to guide the needle during insertion so that the needle can not scrape against the inside wall of the second conduit means.

PATENT- UND RECHTSANWÄLTE
BARDEHLE, PAGENBERG, DOST, ALTENBURG & PARTNER

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C 5165-EP

C L A I M S

1. A connector system for intravenously introducing medication into a patient, comprising:

a cap member having a cavity therein in which is lodged a needle in a manner whereby the needle is recessed within the cavity,

a branch connector having a first inlet port adapted to be connected by tubing means to a source of parenteral liquid, an outlet port through which the parenteral liquid flows via tube means into the patient, and a second inlet port having seal means which is adapted to be penetrated by the needle, said medication flowing from a source through the needle into the parenteral liquid flowing through the connector, and

means coupling the second inlet port and the cap member securely together, with the needle penetrating the seal means, whereby movement of the patient does not result in the removal of the needle from the seal means.

2. The connector system of Claim 1 wherein the internal walls of the cap member guide the needle so that said needle penetrates the central portion of seal means as the cap member is fitted over the second inlet port and does not scrape against the connector.

3. The connector system of Claim 2 wherein the cavity provides a chamber which surrounds the needle, with said needle being lodged within the chamber so that it is not likely to be contaminated.

4. The connector system of Claim 3 wherein the cap member is screwed onto the second inlet port, said cap member having internal threads which engage external threads adjacent the second inlet port.

5. The connector system of Claim 4 wherein the cap member has outwardly extending wings that permit the cap means to be easily screwed onto the second inlet port.

6. A connector system for introducing medication into a patient, comprising:

feeding means through which liquid flows into the patient, said feeding means having a port therein including seal means which close said port, said seal means being adapted to be penetrated by a needle, and

a cap member secured to the port, said cap member having a cavity therein which forms a chamber in which is lodged a needle which does not project beyond an open end of the cavity, said needle penetrating the seal means when the cap

member is covering the port, with said medication being fed through the needle into the liquid flowing into the patient.

7. A connector system used in the treatment of a patient, comprising:

feeding means having a tubular conduit member serving as a male component and having an open end sealed by seal means which close off the open end, said seal means being adapted to be penetrated by a needle, and

a cap member removably secured to the conduit, said cap member serving as a female component and having a cavity therein in which is centrally lodged a needle, said cavity having internal side walls which fit snugly around the tubular conduit member and guide the needle into the central portion of the seal means when the cap member and conduit interact in a male-female mating relationship when the cap is placed on the conduit member.

8. A cap member for connecting a source of medication to a tubular conduit, comprising:

a connector section having a hollow interior which forms a chamber, and

a needle disposed lengthwise within the chamber and of a length such that it does not protrude beyond the chamber.

9. A connector system for coupling a feeding system to a source of medication wherein the feeding system includes a sealed tubular conduit, said device comprising:

a cap member which is adapted to be connected to the tubular conduit and which carries a needle which penetrates the sealed tubular conduit when the cap member is connected to the conduit;

said cap member including means for guiding the needle during insertion so that it can not scrape against the inside wall of the conduit and for protecting the needle from direct contact with objects that may contaminate the needle when the cap member and tubular conduit are disconnected; and

means for securely, but detachably, holding the cap to the tubular conduit.

10. A connector system comprising:

first conduit means having an open end, seal means at the open end of the first conduit and sealing said open end, said seal means being of the type that is adapted to be penetrated by a needle, and

second conduit means having at one end means for coupling the first and second conduits together, said coupling means including a cap member adapted to fit over the end of first conduit means and having a cavity therein which forms a chamber in which is lodged a needle that does not project beyond an open end of the cavity, said needle penetrating the seal means when the first and second conduit means are coupled together.

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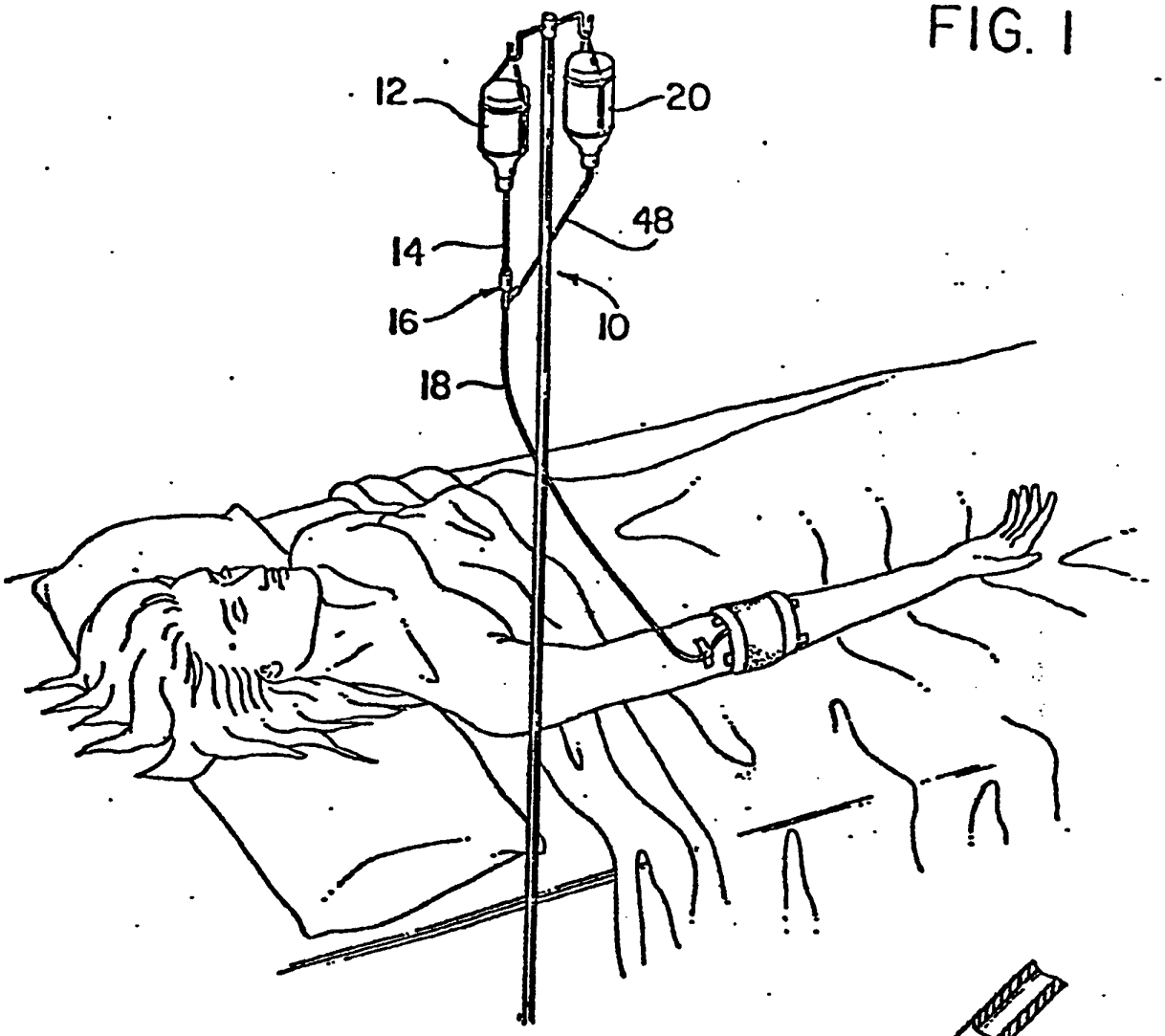
FIG. 1



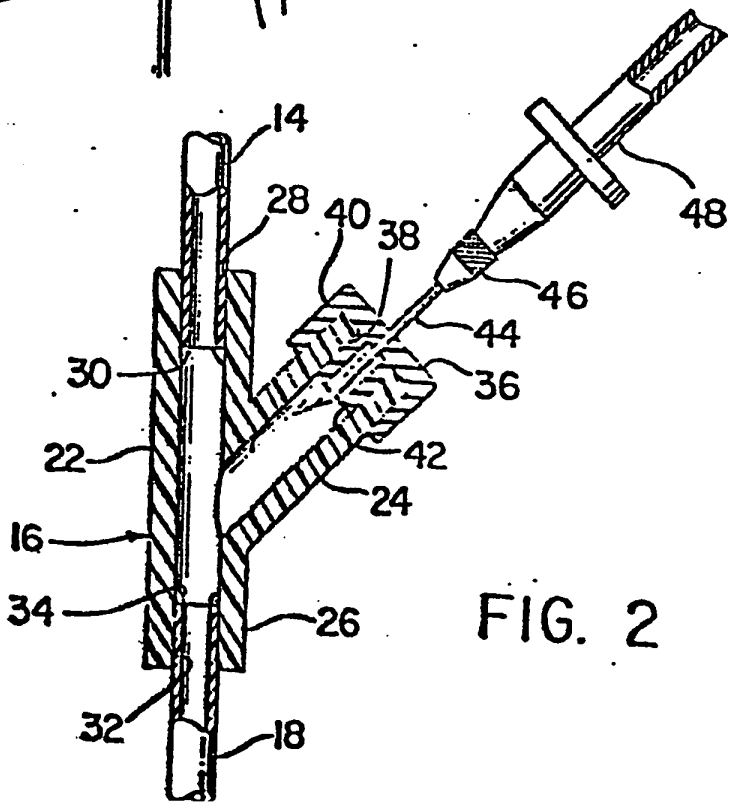


FIG. 2

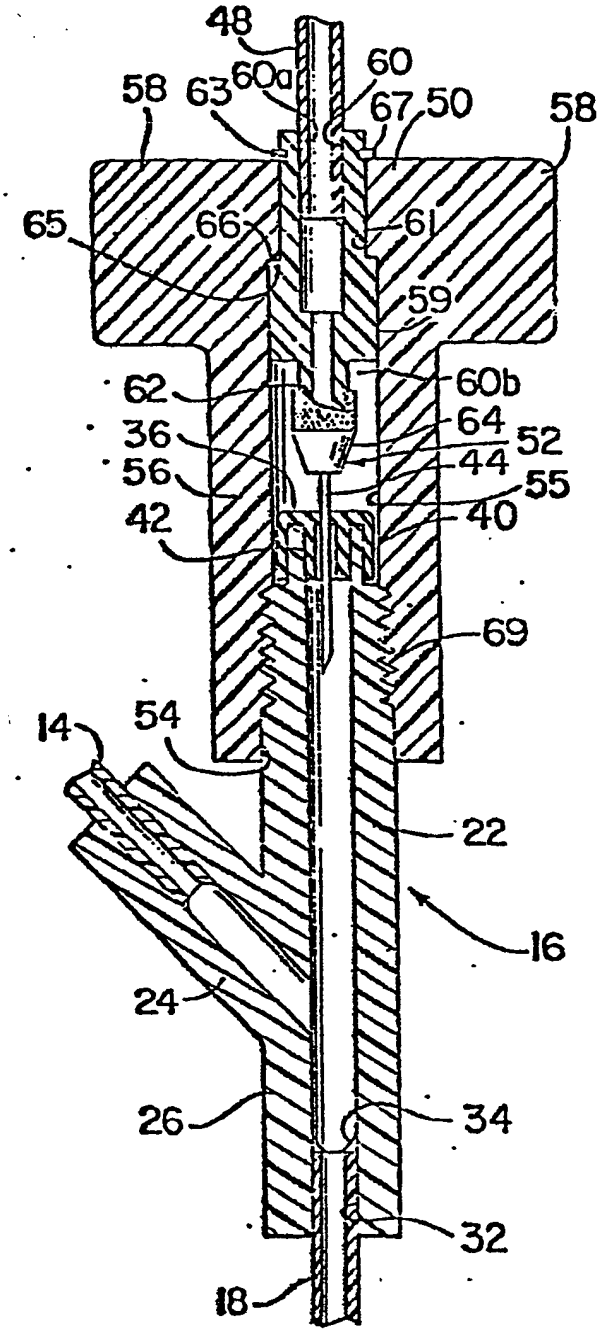


FIG. 4

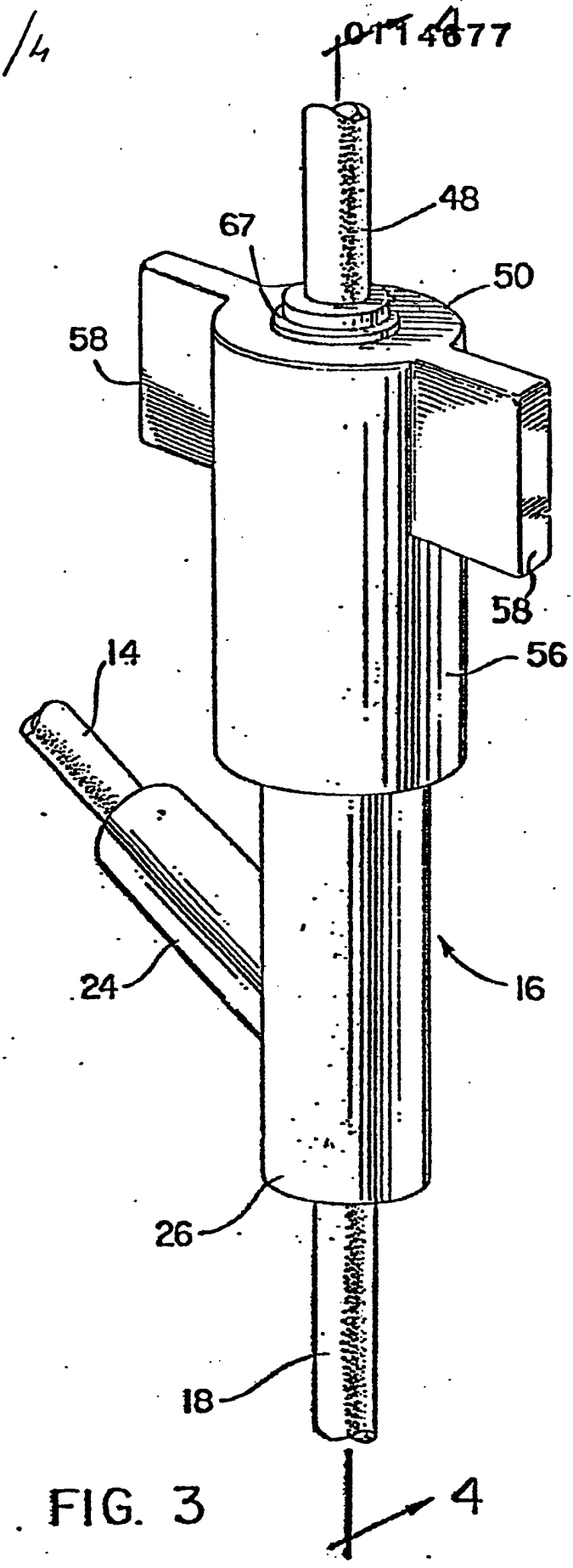


FIG. 3

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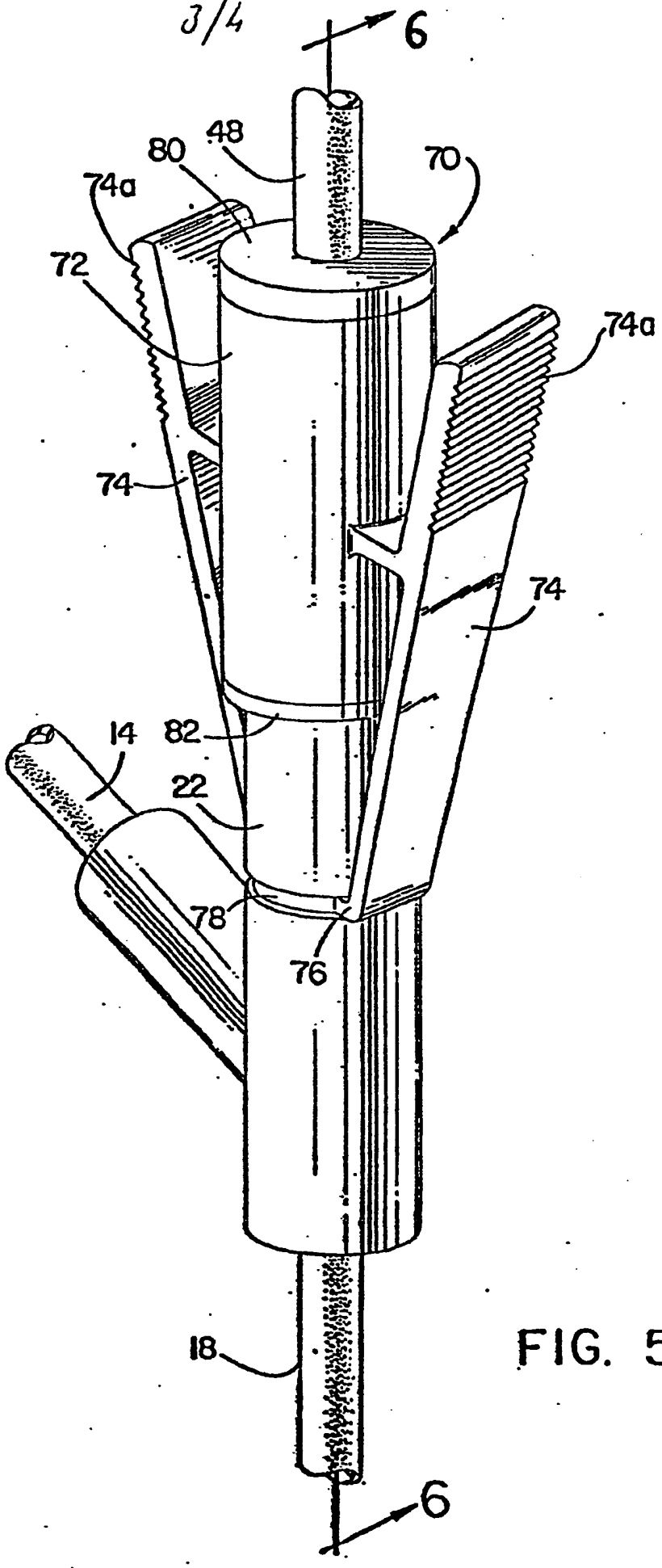

FIG. 5

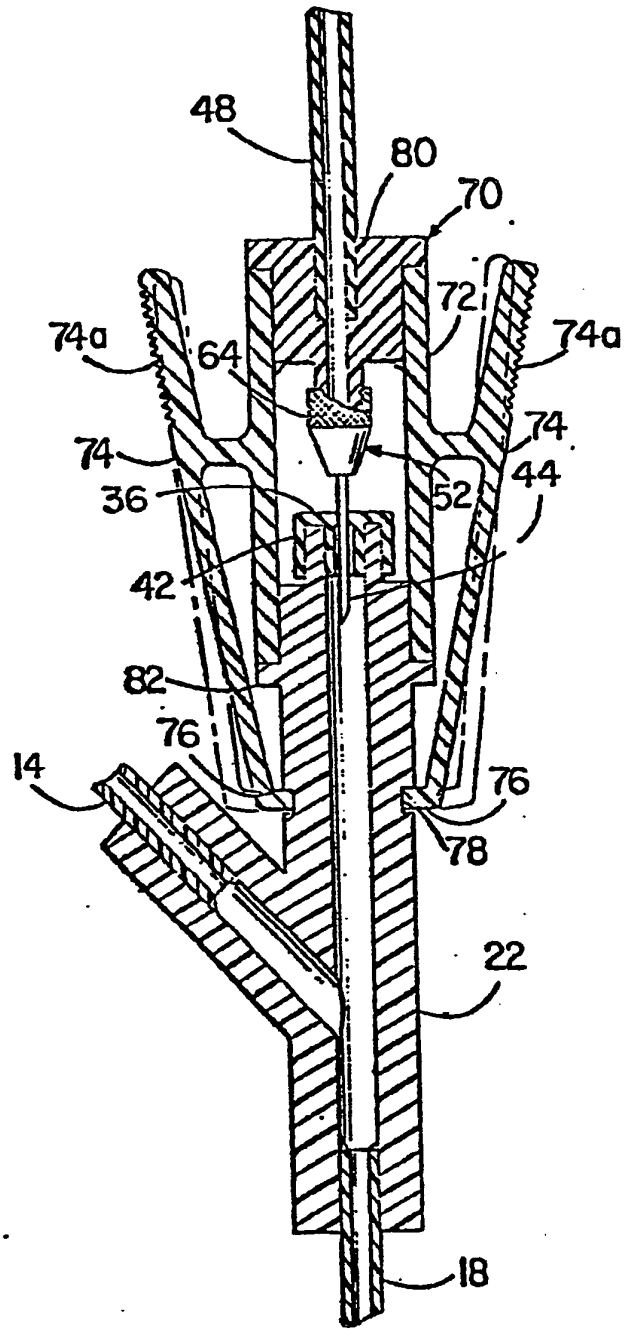

FIG. 6